Offering HIV Testing to Pregnant Women Significant Legislative Rule Analysis WAC 246-100-206, -207, and -208

I. Clearly state in detail the general goals and specific objectives of the statute that the rule implements (RCW 34.05.328(1)(a).

In 1988, the legislature adopted RCW 70.24.095 requiring that "Every health care practitioner attending a pregnant women or a person seeking treatment or a sexually transmitted disease shall insure that AIDS counseling of the pregnant woman is conducted".

At the same time, the legislature in RCW 70.24.380 mandated the state Board of Health to establish minimum standards for "AIDS counseling". In 1989, the Board adopted such rules based on the medical and public health science of the time.

In RCW 70.24.015 the legislature declared the intent of the 1988 AIDS Omnibus law and the control of sexually transmitted diseases (STDs). The legislature found that STDs "result in significant social, health and economic costs, including infant and maternal mortality...". Further the legislature found that "medical knowledge and information...is rapidly changing...". And, the intent of the legislature is "to provide a program that is sufficiently flexible to meet emerging needs..."

This proposed rule amendment fulfills legislative intent by amending Board rules for AIDS counseling of pregnant women based on current medical and public health recommendations and practices. Specifically, all pregnant women will be encouraged to have a test for HIV, not just those assessed to be at high risk.

II. Determine that the rule is needed to achieve the general goals and specific objectives of the authorizing statute (RCW 34.05.328(1)(b)).

As noted above, the legislature in RCW 70.24.380 mandated the state Board of Health to establish minimum standards for "AIDS counseling". This was first accomplished in 1989, these rules are now being updated

In 1995, as a result of studies showing the efficacy of anti-retroviral treatment in reducing perinatal transmission of HIV (from 25% to 8%), many national organizations recommended voluntary HIV testing of all pregnant women. Delivery by caesarian section can further reduce disease transmission.

In 1999, based on findings that some HIV-infected pregnant women are not being tested for HIV because (1) of systemic barriers in the health care delivery system or (2) pregnant women are unaware of or deny risk factors, the Institute of Medicine (IOM) recommends that HIV testing be provided as part of the routine battery of prenatal tests, with an option for the woman to refuse HIV testing. The federal Centers for Disease Control has endorsed the IOM position in there own recommendations, as have national organizations (e.g., American College of Obstetricians and Gynecologists) and state organizations (e.g., Washington State Medical Association).

This rule amendment revises standards for "AIDS counseling to be more consistent with the recommendations of federal agencies and national/state organizations. This proposed rule amendment fulfills legislative intent as expressed in RCW 70.24.015.

III. Determine that the probable benefits of the rule are greater than its probable costs (RCW 34.05.328(1)(c).

Direct Costs

The Department has determined that there are no direct increased costs for this proposed rule revision. In fact, clarifying that consent for HIV testing may be verbal (or in writing) may reduce health care practitioner costs associated with obtaining a separate written consent for HIV testing.

Indirect Costs

While the proposed rule revision does not require HIV testing of any person, it is likely the requirement to offer and encourage all pregnant women to have a test for HIV will increase the number of women who voluntarily choose to be tested. As the proposed rule recommends that HIV testing be done at the same time the pregnant woman receives other routine tests, the only additional cost is associated with laboratory processing.

Probable Annual Costs of Increased Laboratory Testing

Number of Live Births (2000)	81,004
Estimated Percent Tested for HIV ¹	59%
Estimated Number of HIV Tests in 2000	47,792
Projected Percent Tested for HIV with Rule Revision	90%
Projected Number of HIV Tests in Future Years	72,904
Increased Number of HIV Tests	25,111
HIV Antibody Laboratory Costs ²	\$12.00
Probable Increased Costs	\$301,335

Probable Annual Benefits of Increased Laboratory Testing

Number of Pregnant Women Newly Tested for HIV Estimated Seroprevalence of HIV ³ Estimated Number of HIV-infected Pregnant Women	25,111 .051% 11
Number of Infants Born with HIV Without Maternal Treatment (25%) Number of Infants Born with HIV With Maternal Treatment (8%)	3 (2.74) 1 (0.88)
Cost of Care and Treatment for HIV-infected Infant (to age 10 based on present value calculator) ⁴	\$279,710
Cost of Care for 3 Infected Infants	\$839,130
Cost of Care for 1 Infected Infants Probable (Cost Saving) Benefits	\$279,710 \$559,420

Washington State HIV/AIDS Knowledge, Attitudes and Belief Survey, Department of Health, 2000

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² Uniform Medical Benefit is \$15, Medicaid is about \$9. \$12 was chosen as an average.

³ 1995 Survey of Child-Bearing Women, Washington State Department of Health

⁴ See attached Cost of HIV Care worksheet.

IV. Determine, after considering alternative versions of the rule, that the proposed rule is the least burdensome alternative for those required to comply with it that achieves the goals and objectives of the authorizing statute (RCW 34.05.328(1)(d).

Those required to comply with this rule are health care practitioners attending pregnant women. This amendment revises state rules to more closely align with federal recommendations and the recommendations of state and national organizations. Not revising the rule would be more burdensome to health care practitioners and insurers. Mandating HIV testing of pregnant women was considered, but rejected because the Board of Health does not have such authority and it would be inconsistent with federal and national recommendations.

The proposed rule achieves the goals and objectives of the authorizing statute by contributing to the prevention of maternal and infant mortality and by being responsive to changes in medical knowledge.

V. Determine that the proposed rule does not violate any other federal or state statute (RCW 34.05.0328(1)(e).

The proposed rules are not in violation of another federal or state law. The proposed rule is consistent with federal recommendations.

VI. Determine that the proposed rule does not impose more stringent performance from private entities than public entities (RCW 34.05.328(1)(f).

Any proposed performance requirements would apply equally to all health care practitioners attending a pregnant woman.

VII. Determine that the rule does not differ from federal regulation or statute, which is applicable to same activity or subject matter, or justify difference (RCW 34.05.328(1)(g).

There are no known federal regulations that regulate this same activity. The proposed rule is consistent with federal recommendations.

VIII. Determine that the rule is coordinated, to the maximum extent practicable, with other federal, state and local laws applicable to the same activity or subject matter (RCW 34.05.328(1)(h).

The document Revised Guidelines for HIV Counseling, Testing and Referral and Revised Recommendations for HIV Screening of Pregnant Women, November 9, 2001 published by the federal Centers for Disease Control and Prevention was reviewed extensively in drafting proposed changes to this rule.

Attachment - Cost of HIV infection in one infant, 2000⁵

Year	Year of Life	HIV Symptoms	Undiscounted Costs	Combination Therapy Added ⁶	Total Cost	Present Value Multiplier	Present Value Costs
2002	1	None	\$ 2,034	\$ 3,945 ⁷	\$ 5,979	1.0000	\$ 5,979.00
2003	2	Mild HIV	\$13,110	\$ 4,626	\$17,736	0.9702	\$17,207.72
2004	3	Moderate HIV	\$13,563	\$ 4,877	\$18,440	0.9413	\$17,357.87
2005	4	Moderate HIV	\$13,563	\$ 5,916	\$19,479	0.9133	\$17,789.75
2006	5	Moderate HIV or AIDS	\$21,136	\$ 6,664	\$27,800	0.8861	\$24,362.91
2007	6	AIDS	\$43,860	\$ 7,543	\$51,403	0.8597	\$44,190.31
2008	7	AIDS	\$43,860	\$ 8,486	\$52,346	0.8341	\$43,660.61
2009	8	AIDS	\$43,860	\$ 9,327	\$53,187	0.8092	\$43,040.72
2010	9	AIDS	\$43,860	\$10,505	\$54,365	0.7851	\$42,683.61
2011	10	AIDS/Death	<u>\$18,223</u>	<u>\$12,191</u>	<u>\$30,414</u>	0.7617	<u>\$23,167.71</u>
Total			\$257,069	\$74,080	\$331,149		\$279,710.22

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⁵ Table based on Gorsky, Guinan et al, "Preventing Perinatal Transmission of HIV – Costs and Effectiveness of a Recommended Intervention". Public Health Reports Vol III, July/Aug 1996. Costs have been modified by a compounded inflationary factor of 3.7%.

⁶ The above-referenced study was completed in 1996, prior to the advent of additional therapies (combination therapy) for HIV.

⁷ Costs are for two additional medications at the AWP cost, with cost increases projected at 3.7% per year away from the start year. The two medications were picked at random from the list of combination therapy. This does not reflect the cost of adding protease inhibitors (which may become state-of-the-art for older children.)